ATTACHMENT 41

Joe Morrison

From: Ryan Burke <rburke@ajwtech.com>
Sent: Thursday, July 09, 2015 2:32 PM
To: Joe Morrison; Jeff Bua; Jon Ward
Subject: Fwd: RE: Rebotix AI Letter Conference Call Follow-Up

---------- Forwarded message ----------
From: "Wen, Mary" <Mary.Wen@fda.hhs.gov>
Date: Jul 9, 2015 2:06 PM
Subject: RE: Rebotix AI Letter Conference Call Follow-Up
To: Ryan Burke <rburke@ajwtech.com>
Cc: "'k143619@docs.fda.gov'" <k143619@docs.fda.gov>

Hi Ryan,

Please find our responses to your questions below. If you'd like further clarification on these responses, please let me know if you'd like to set up a teleconference to discuss.

Best wishes,

Mary Wen, Ph.D.

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From: Ryan Burke [mailto:rburke@ajwtech.com]
Sent: Tuesday, June 30, 2015 4:22 PM
To: Wen, Mary
Cc: 'k143619@docs.fda.gov'
Subject: Rebotix AI Letter Conference Call Follow-Up

Dear Dr. Wen,

We would like to again thank you for making time to speak to us yesterday morning, and for the clarification and insight that you have offered. Despite the apparent magnitude of the deficiency letter, we were encouraged by your willingness to work with us interactively through the process.

As a follow-up to the call, this message is intended to further describe the issues that we discussed, so that clarification might be solicited from members of the review team, as appropriate.

Below I have detailed our concerns over certain stated deficiencies that we believe threaten the feasibility of moving forward. In each case, I have striven to present our point of view in detail, so that any discrepancies in perspective can be recognized. In each case, it could be that we are just not properly understanding what FDA is requesting, so any clarification that you can provide to us would be immensely helpful. We see these as "the big questions" that need to be addressed before any more progress can be made on our side.

Best Regards,

-Ryan

Ryan Burke, RAC

Regulatory and Quality Consultant

AJW Technology Consultants, Inc.

Subject: Tracking Reprocessing History

RAI questions 3b(ii), 6b, 18, 35a, 39, and 42b all make reference to FDA's expectation that we should have knowledge of how the returned used devices were previously reprocessed by the end user. Specifically (3b(ii)), "FDA expects that you collect and track information from the health care facilities and only accept devices that fit within the scheme of devices that were validated for remanufacturing…" and (6b), "These recalls underscore the importance of tracking the reprocessing history of all incoming devices (i.e., tracking how these devices were reprocessed by the previous end user prior to re-manufacture)." Knowledge of reprocessing history is also noted as important for establishing worst case for sample selection in (18) Cleaning Validation, (35a) Biocompatibility Testing, (39) Electrical Safety/EMC Testing, and (42b) Performance Testing.

The emphasis on this theme in the AI Letter was hard to miss. However, we have deep concerns about how FDA's expectations, as we read them, could be feasibly implemented. For example, our ability to "collect and track information from the health care facilities" is limited. It may be feasible to get some level of attestation from the user facility that they complied with OEM reprocessing guidelines. However, unless they acknowledged it to us, we could never actually know if they deviated from the guidelines or applied additional cleaning processes that were not recommended in OEM labeling (any more than the OEM could be expected to know this). As such, our validation activities were based on the assumption that previous end users had followed OEM reprocessing instructions. It was also unclear to us how, "the OEM's reprocessing instructions could be implemented differently at the health care facilities." If the expectation is that we somehow track the specific reprocessing history of each OEM EndoWrist and account for all reprocessing parameters before we can remanufacture it, then we do not believe this will be feasible. We would also question why such a deep accounting is necessary when reasonable worst case reprocessing can readily be defined.

On the call (with Dr. Wen) yesterday, you explained that an optional disinfection step that was added in the updated IFU may have been the context for these deficiencies. If the expectation is actually just that we understand which OEM reprocessing instructions were followed by the previous end user (e.g. what version of IFU was the basis, whether optional processes were applied, etc.), then we understand and see this as reasonable. In consideration of our initial interpretation of expectations expressed in these six deficiencies, any clarification that you can provide would be greatly appreciated.

RESPONSE: Our concern with the tracking of the reprocessing methods used by the end user on the previous used devices stems from the fact that the OEM can make labeling changes that include changes to the reprocessing instructions. These reprocessing changes could affect the additional device use lives validated by Rebotix. We agree that Rebotix should understand which OEM reprocessing instructions were followed by the previous end user (e.g., what version of the IFU was the basis, whether optional processes (e.g., disinfection, etc.) were applied, etc.) and track this with the incoming devices. If any used devices are received that were reprocessed under processes that were not included in the validation studies performed by Rebotix, these devices should be rejected on incoming inspection.

Subject: Native Soil Characterization and Testing

RAI questions 3b(i), 18, and 19 variously describe the need for a Native Soil Characterization Study. It is also (19) recommended, "that only worst

case natively soiled devices be used in your cleaning and sterilization validation studies. We read "natively soiled" to mean soiled by actual clinical use (as opposed to "artificial soil" that we understand is typically used for such testing). If this is what was intended, then we have practical concerns about even obtaining such soiled devices from user facilities for testing, as well as how they could be safely handled, how to gather enough "worst case natively soiled" sample devices for testing, and how much information we could even obtain about the specific procedures they were used in.

The referenced FDA guidance, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling", recommends that, "The manufacturer should select an artificial test soil, the composition of which accurately represents materials that the device would likely be exposed to during an actual clinical use, and would create the greatest (worst-case) challenge to the cleaning process." The guidance gives an example of how artificial test soils for a laryngoscope would be selected based on its intended use, to include substances that simulate both blood and mucus. We agree with FDA in this guidance that this is a reasonable approach. However, the guidance makes no mention of Native Soil Characterization Studies, or of testing on natively soiled devices, and we are struggling to understand the basis for this stated requirement.

Unless we are misunderstanding the meaning of "Natively Soiled" (and if so, please feel free to correct our understanding), we believe that performing cleaning validations on natively soiled devices is probably not

feasible. Based on our reading of current FDA guidance, we are also having trouble understanding why this is being recommended at all, as it seems to imply that the methods recommended in current FDA guidance are inadequate. Obviously, we find this troubling, and any clarification that you can provide would be extremely helpful.

RESPONSE: By "natively soiled", we do mean soiled by actual clinical use. The recommendations to perform a Native Soil Characterization Study stem from the fact that the device is not simply a reusable device, but is a third party reprocessed/remanufactured device. Similar to third party reprocessors who reprocess single-use devices, our expectation is that Rebotix would have an understanding of the native soil present on incoming devices and that only devices with soil levels that had been used in the validation studies are accepted at incoming inspection. Since the soil of the devices should also be tracked, if any devices are received that do not meet established acceptance criteria for soil (e.g., are soiled beyond the devices used in the validation studies), then they should be rejected. As a clarification, while the "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" Guidance does apply to reusable devices, the subject device is a third party reprocessed device that is not explicitly covered by the Guidance. See the related "Exclusions" section in the referenced Guidance. Third party reprocessors commonly perform a Native Soil Characterization Study to ensure that their validation studies are relevant and to set limits for their incoming device inspection criteria. Typically, clinically used and worst case soiled devices (i.e., worst case natively soiled and worst case artificially soiled) are used in the validation studies performed by third party reprocessors.

Subject: Bioburden

RAI question 32g requests results from bioburden enumeration and resistance, or a description of routine bioburden monitoring with action/alert limits, as well as a qualification of BI's "used for routine cycle monitoring". The question is puzzling to us as, just like the OEM versions, the Remanufactured EndoWrists are supplied non-sterile and without sterile packaging. Further, the sterilization cycle recommended was validated by the conservative overkill method (ISO 17665-1:2006 Annex D), which is widely employed for reprocessing reusable devices. According to this FDA-recognized standard, the overkill method does not require knowledge of the bioburden (which would seem appropriate since it is not reasonable to predict potential bioburden exposure at a user facility).

After the call (with Dr. Wen) yesterday morning, it was suggested internally that it may have appeared in the submission as though we were planning to provide a sterile accessory, such as the tip cover. Our intent is that the submission only cover the Remanufactrured EndoWrists, as we do not intend to provide any of the accessories. Please let us know if this misunderstanding was the source of the bioburden deficiency question. (We intend to revise the labeling to clarify that we will not be providing any of these accessories.) If this was not the source of the noted deficiency, then please help us understand how the bioburden concerns apply to the remanufactured EndoWrists.

RESPONSE: Although the device is not supplied sterile to the end user, reprocessing (including sterilization) is performed at the Rebotix facility. Since the incoming device is a clinically used device with variable levels of

bioburden and potentially high levels of bioburden (e.g., devices used in colorectal procedures), it is recommended to perform the bioburden testing and monitoring described in AI Question 32g to ensure the sterilization process is effective. This type of testing and monitoring is routinely performed by third party reprocessors due to the variable nature of the starting product.